

107TH CONGRESS  
2D SESSION

# S. 3130

To amend the Federal Food, Drug, and Cosmetic Act to add requirements regarding device reprocessing and reuse.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2002

Mr. DURBIN (for himself and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to add requirements regarding device reprocessing and reuse.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Reprocessed Med-  
5 ical Devices Act of 2002”.

6 **SEC. 2. PURPOSE.**

7 The purpose of this Act is to—

8 (1) increase the safety and medical devices la-  
9 beled as single-use devices that are reprocessed for  
10 additional use;

1           (2) provide health professionals with more accu-  
2       rate information on the medical devices that they are  
3       using; and

4           (3) provide the Food and Drug Administration  
5       with more accurate information on adverse events  
6       that may be caused by device failure.

7   **SEC. 3. DEVICE REPROCESSING AND REUSE.**

8       (a) IN GENERAL.—Section 502 of the Federal Food,  
9   Drug, and Cosmetic Act (21 U.S.C. 352) is amended by  
10   adding at the end the following:

11       “(u)(1) The reprocessing for reuse of a device (in-  
12   cluding the manufacture or repeated manufacture of a  
13   previously used device) that is intended for use on a single  
14   patient, unless such reprocessed device—

15           “(A)(i) is subject to an order under section 515  
16       approving the reprocessed device as safe and effec-  
17       tive for the number of intended uses by the reproc-  
18       essor as set forth in its submission, or

19           “(ii) is subject to an order determining that the  
20       reprocessed device is substantially equivalent under  
21       subsections (f) and (i) of section 513 to a legally  
22       marketed device, specifically taking into account the  
23       number of uses specified in the label of the reproc-  
24       essed device;

1           “(B) is labeled with the number of times the  
2       device has been reprocessed;

3           “(C) prominently and conspicuously bears the  
4       name of the reprocessor and the original manufac-  
5       turer of the device, a generally recognized abbrevia-  
6       tion of such names, or a unique and generally recog-  
7       nized symbol identifying such manufacturers, except  
8       that the Secretary may waive any requirement under  
9       this subparagraph with respect to a device if the  
10      Secretary determines that compliance with the re-  
11      quirement is not feasible or would compromise the  
12      provision of reasonable assurance of the safety or ef-  
13      fectiveness of the device; and

14          “(D) prominently and conspicuously bears on  
15      its label the following statement: ‘Reprocessed device  
16      for single use reprocessed by \_\_\_\_\_’,  
17      (the name of the reprocessor shall be placed in the  
18      blank space to identify the person responsible for re-  
19      processing).

20          “(2)(A) Not later than 60 days after the date of en-  
21      actment of this subsection, the Secretary shall review each  
22      reprocessed device that is exempt on such date from the  
23      requirement to submit a report under section 510(k) and  
24      shall—

1           “(i) in the case of an exempt class I reprocessed  
2       device, determine whether the device is intended for  
3       a use which is of substantial importance in pre-  
4       venting impairment of human health or presents a  
5       potential unreasonable risk of illness or injury, in-  
6       cluding a review of the risks presented by reprocess-  
7       ing the device; and

8           “(ii) in the case of an exempt class II repro-  
9       cessed device, determine whether such a report is nec-  
10      essary to assure the safety and effectiveness of the  
11      devices, including a review of the risks presented by  
12      reprocessing the device.

13   The Secretary shall solicit public comment during such 60  
14   day period concerning whether each device should remain  
15   exempt.

16       “(B) Based on the finding of the review conducted  
17   under subparagraph (A) the Secretary shall, not later than  
18   120 days after such date of enactment, publish in the Fed-  
19   eral Register a list of the reprocessed devices that are no  
20   longer exempt from submission of a report under section  
21   510(k). The reprocessor of any such device will be re-  
22   quired to make a submission under section 510(k) not  
23   later than 120 days after the publication by the Secretary  
24   of such list in the Federal Register.

1       “(C) During such 120-day period, the Secretary may  
2 not determine that the device is misbranded under sub-  
3 section (o) or adulterated under section 501(f)(1)(B) on  
4 the basis that such report has not been submitted to the  
5 Secretary. After the submission of the report to the Sec-  
6 retary, the Secretary may not determine that the device  
7 is misbranded under subsection (o) or adulterated under  
8 section 501(f)(1)(B) until the Secretary determines the  
9 classification of the device under section 513 or the Sec-  
10 retary determines that the submission was insufficient to  
11 make a classification.

12       “(D) Subsection (o) applies with respect to a failure  
13 to submit a report under subsection (k) that is required  
14 pursuant to subparagraph (A), including a failure of the  
15 report to include validation data required in such subpara-  
16 graph.

17       “(E) The termination under subparagraph (A) of an  
18 exemption under subsection (l) or (m) for a reprocessed  
19 device does not terminate the exemption under subsection  
20 (l) or (m) for the original device.

21       “(v) The introduction or delivery for introduction into  
22 interstate commerce of a device which was previously used  
23 in a patient and labeled in a manner that represents di-  
24 rectly or indirectly that the device is new or unused.”.

1 (b) EXEMPTIONS.—Section 510 of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

3 (1) in subsection (l), by adding at the end the  
4 following: “The Secretary, in determining whether  
5 an exemption under this subsection applies, shall  
6 consider whether such an exemption would also  
7 apply to such a device when reprocessed with consid-  
8 eration given to whether additional risks, if any,  
9 from reprocessing should preclude such an exemp-  
10 tion.”; and

11 (2) in subsection (m), by adding at the end the  
12 following:

13 “(3) The Secretary in determining whether an ex-  
14 emption under this subsection applies shall consider  
15 whether such an exemption would also apply to such a  
16 device when reprocessed with consideration given to  
17 whether additional risks, if any, from reprocessing should  
18 preclude such an exemption.”.

19 (c) PREMARKET NOTIFICATION.—Section 510 of the  
20 Federal Food, Drug and Cosmetic Act (21 U.S.C. 360)  
21 is amended by adding at the end the following:

22 “(o) With respect to reprocessed single-use devices  
23 for which reports are required under subsection (k):

24 “(1)(A) The Secretary shall identify such de-  
25 vices or types of devices for which reports under

1       such subsection must, in order to ensure that the de-  
2       vice is substantially equivalent to a predicate device,  
3       include validation data, the types of which shall be  
4       specified by the Secretary, regarding cleaning and  
5       sterilization, and functional performance dem-  
6       onstrating that the single-use device will remain sub-  
7       stantially equivalent to its predicate device, after the  
8       maximum number of times the device is reprocessed  
9       as intended by the person submitting the premarket  
10      notification.

11           “(B) Not later than 60 days after the date of  
12      enactment of this subsection, the Secretary shall  
13      publish in the Federal Register a list of the device  
14      types identified under subparagraph (A), and shall  
15      revise the list as appropriate.

16           “(C) Reports under subsection (k) for devices  
17      or types of devices within a type included on the list  
18      under subparagraph (B) are, upon publication of the  
19      list, required to include such validation data.

20           “(2)(A) In the case of each report under sub-  
21      section (k) that was submitted to the Secretary prior  
22      to the publication of the initial list under paragraph  
23      (1), or any revision thereof, and that was for a de-  
24      vice or type of device included on such list, the per-  
25      son who submitted the report under subsection (k)

1 shall submit validation data as described in para-  
2 graph (1) to the Secretary not later than 9 months  
3 after the publication of the list under paragraph  
4 (1)(B).

5 “(B) During the 9-month period described in  
6 subparagraph (A), the Secretary may not take any  
7 action under this Act against a device solely on the  
8 basis that the validation data for the device has not  
9 been submitted to the Secretary.

10 “(C) After the submission of the validation data  
11 to the Secretary, the Secretary may not determine  
12 that the device is misbranded under section 502(o)  
13 adulterated under section 501(f)(1)(B), or take ac-  
14 tion against the device under section 301(p) for fail-  
15 ure to provide any information required by sub-  
16 section (k) until—

17 “(i) the review is terminated by withdrawal  
18 of the submission of the report under sub-  
19 section (k);

20 “(ii) the Secretary finds the data to be ac-  
21 ceptable and issues a letter; or

22 “(iii) the Secretary determines that the de-  
23 vice is not substantially equivalent to a predi-  
24 cate device.



1           Upon a determination that a device is not sub-  
2           stantially equivalent to a predicate device under  
3           clause (iii), the device may no longer be legally mar-  
4           keted.

5           “(3) In the case of a report under subsection  
6           (k) for a device identified under paragraph (1) that  
7           is of a type for which the Secretary has not pre-  
8           viously received a report under such subsection, the  
9           Secretary may, in advance of revising the list under  
10          paragraph (1) to include such type, require that the  
11          report include the validation data specified in para-  
12          graph (1).

13          “(4) Section 502(o) applies with respect to the  
14          failure of a report under subsection (k) to include  
15          validation data required under paragraph (1).”.

16          (d) DEFINITIONS.—Section 201 of the Federal Food,  
17          Drug, and Cosmetic Act (21 U.S.C. 321) is amended by  
18          adding at the end the following:

19          “(ll) The term ‘single-use device’ means a disposable  
20          device that is intended for one use or use on a single pa-  
21          tient in a single procedure.

22          “(mm)(1) The term ‘reprocessed’, with respect to a  
23          single-use device, means an original device that was used  
24          as intended and then subsequently was subject to addi-  
25          tional processing and manufacturing for the purpose of

1 an additional single use on a patient. The subsequent  
2 processing and manufacture of a reprocessed single use  
3 device shall result in a device that is reprocessed within  
4 the meaning of this definition.

5 “(2) A single-use device that meets the definition  
6 under paragraph (1) shall be considered a reprocessed de-  
7 vice without regard to any description of the device used  
8 by the manufacturer of the device or other persons, includ-  
9 ing a description that uses the term ‘recycled’ rather than  
10 the term ‘reprocessed’.

11 “(nn) The term ‘original device’ means a new, unused  
12 single use device.”.

13 **SEC. 4. MEDWATCH.**

14 Not later than 6 months after the date of enactment  
15 of this Act, the Secretary of Health and Human Services  
16 shall modify the MEDWATCH voluntary and mandatory  
17 forms to facilitate the reporting of information by user fa-  
18 cilities or distributors as appropriate relating to repro-  
19 cessed devices, including the name of the reprocessor and  
20 whether the device has been reused.

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